OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS

Bureau of Competition
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FTC ANTITRUST ACTIONS INVOLVING PHARMACEUTICAL SERVICES AND PRODUCTS[1]

I. INTRODUCTION

The Federal Trade Commission is a law enforcement agency charged by Congress with protecting the public against anticompetitive behavior and deceptive and unfair practices. The FTC's antitrust arm, the Bureau of Competition, is responsible for investigating and prosecuting "unfair methods of competition" which violate the FTC Act. The FTC shares with the Department of Justice responsibility for prosecuting violations of the Clayton Act.

When litigation becomes necessary, many of the FTC's adjudicative matters are conducted in administrative adjudication before an FTC Administrative Law Judge. This provides the opportunity for matters raising complex legal and economic issues to be heard, in the first instance, in a forum specially suited for dealing with such matters. Appeals from Commission decisions are taken directly to the federal courts of appeal. The Commission also has the authority to seek a preliminary injunction in federal district court whenever the Commission has reason to believe that a party is violating, or is about to violate, any provision of law enforced by the FTC. Such preliminary injunctions are intended to preserve the status quo, or to prevent further consumer harm, pending administrative adjudication before the Commission. Additionally, the Commission has the authority to seek a permanent injunction in federal district court in a "proper case" pursuant to section 13(b) of the FTC Act.

In the mid-1970s, the FTC formed a division within the Bureau of Competition to investigate potential antitrust violations involving health care. The Health Care Services and Products Division consists of approximately thrity-five lawyers and investigators who work exclusively on health care antitrust matters. Health Care Services and Products Division staff also work with staff in the FTC's seven regional offices on health care matters. Non-merger matters involving the pharmaceutical industry are investigated by the Health Care Services and Products Division staff. Mergers in the pharmaceutical industry are investigated by the Mergers I Division. FTC cases involving pharmaceutical services and products are summarized below.[2] The Commission and its staff have also responded to numerous requests for guidance from health care industry participants through, among other things, the advisory opinion letter

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[1] This summary has been prepared by the FTC Health Care Services and Products Division staff, and has not been reviewed or approved by the Commission or the Bureau of Competition. Section III describes FTC enforcement involving mergers in the pharmaceutical industry, which are primarily conducted by the Mergers I Division of the Bureau of Competition.

[2] Commission orders issued since March, 1996 are available at the FTC's World Wide Web site at http://www.ftc.gov.

process, and through the issuance of statements on enforcement policy.[3] Although the statements on enforcement policy are more specifically focused on collaborative actions by physicians and hospitals, the basic principles of these statements on enforcement policy can be instructive to the pharmaceutical industry as well.[4]

For further information about matters handled by the FTC's Health Care Services and Products Division and Mergers I Division, or to lodge complaints about suspected antitrust violations, please write, call, or fax as follows:

Non-Merger Matters:

Mailing Address:	Health Care Services and Products Division Bureau of Competition Federal Trade Commission Washington, D.C. 20580
Telephone Number:	202-326-2756
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Merger Matters:

Mailing Address:	Mergers I Division Bureau of Competition Federal Trade Commission Washington, D.C. 20580
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[3] Information regarding advisory opinions is set forth in the Topic And Yearly Indices of Health Care Advisory Opinions By Commission And By Staff. These indices can be obtained from the FTC Public Reference Section. The index, and the advisory opinions issued since October, 1993, are also available at the FTC's World Wide Web site at http://www.ftc.gov.

[4] Statements of Antitrust Enforcement Policy in Health Care, issued on August 28, 1996, 4 Trade Reg. Rep. (CCH) ¶13,153; Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust, issued on September 27, 1994, 4 Trade Reg. Rep. (CCH) ¶13,152; and Department of Justice and Federal Trade Commission Antitrust Enforcement Policy Statements in the Health Care Area, issued on September 15, 1993, 4 Trade Reg. Rep. (CCH) ¶13,151. The 1996 Policy Statements are available at the FTC's web site.

II. CONDUCT INVOLVING PHARMACEUTICAL SERVICES AND PRODUCTS

A. Monopolization

1. **Bristol-Myers Squibb Company**, C-4076 (consent order issued April 14, 2003) (FTC Commission Actions: April 18, 2003 (www.ftc.gov)). The Commission charged in its complaint that Bristol engaged in a pattern of anticompetitive activity over the past decade in order to delay generic competition and maintain its monopoly over three highly profitable branded drugs with total net annual sales of two billion dollars. As a result of Bristol's illegal conduct, consumers paid hundreds of millions of dollars in additional costs for these prescription drugs. The drugs named in the complaint were the anti-anxiety drug, BuSpar, and two anti-cancer drugs, Taxol and Platinol. The pattern of illegal activity involved misusing regulations set up by Congress to hasten the approval of generic drugs, misleading the FDA and the U.S. Patent and Trademark Office in order to protect patents on these branded drugs, and filing baseless patent infringement lawsuits against would be generic competitors. As detailed in the complaint, the anticompetitive activities involving BuSpar included: paying a would-be generic competitor $72.5 million to settle patent litigation, thereby preventing the introduction of a generic BuSpar; filing false information with the FDA in order to list a patent in the Orange Book, thereby automatically obtaining additional 30-month stays; and filing baseless patent infringement suits against potential generic competitors. The complaint alleged that Bristol engaged in similar types of activities with Taxol, a chemotherapy drug originally developed and funded by the National Cancer Institute, which had given Bristol exclusive marketing rights. This conduct including improperly listing three patents in the Orange book, filing misrepresentative statements with the FDA, and entering into an unlawful agreement with a generic competitor in order to obtain an additional 30-month stay on FDA approval of generic Taxol. Similarly, according to the complaint, Bristol engaged in the same type of unlawful activities involving another chemotherapy drug, Platinol, that also included wrongfully submitting a patent for listing in the Orange Book, and filing patent infringement lawsuits against each of four potential generic entrants, resulting in the delay of a generic Platinol.

The order contains general prohibitions concerning conduct relating to Orange Book listings (detailed in the Commission's recent study, *Generic Drug Entry Prior to Patent Expiration*), enforcement of patents, and the settlement of patent litigation when that conduct is designed to delay or prevent generic competition. For example Bristol is prohibited from late listing patents after competitors have filed applications with the FDA for generic entry. The order also contains prohibitions relating specifically to the listing and enforcement of patents relating to Taxol and BuSpar, including listing any patent in the Orange Book relating to products with the same active ingredient, or taking any action that would trigger an additional 30-month statutory stay on final FDA approval of a generic form of Taxol or BuSpar (the order does not provide specific relief for Platinol because a court held the only unexpired patent on Platinol was invalid).

2. **Biovail Corporation,** C-4060 (consent order issued October 2, 2002) (FTC Commission Actions: October 4, 2002 (www.ftc.gov)). The complaint charged that Biovail illegally acquired the exclusive license to a drug patent in order to prevent generic competition from ending its monopoly in the antihypertension drug Tiazac. Biovail then wrongfully listed the acquired patent as claiming Tiazac in the FDA's Orange Book in order to maintain its monopoly. As a result of the Orange Book listing and other conduct, including making a misleading statement to the FDA during the regulatory process, the complaint alleged that Biovail sought to illegally delay the entry of generic Tiazac by gaining a second 30-month stay on generic entry through patent infringement litigation. The order requires Biovail to divest part of the exclusive rights of the acquired patent back to DOV Pharmaceuticals, the original owner. In addition, the order prohibits Biovail from taking any action that would trigger an additional statutory stay on final FDA approval of a generic form of Tiazac. The order also prohibits Biovail from wrongfully listing any patents in the Orange Book.

B. Agreements Not to Compete

1. **Perrigo Company and Alpharma Inc.**, Civil Action No. 1:04CV01397 (RMC) (D.C.D.C.), (complaint filed August 17, 2004) (FTC Commission Actions: August 12, 2004 (www.ftc.gov)). In a complaint seeking injunctive and other relief filed in U.S. District Court for the District of Columbia, the Commission charged two generic drug manufacturers, Alpharma, Inc. and Perrigo Company, with entering into an agreement to limit competition for over-the-counter store-brand children's liquid Ibuprofen. The two companies were the only manufacturers of over-the-counter store-brand children's liquid Ibuprofen approved by the FDA. Fifty state attorneys general also filed a similar complaint in U.S. District Court. According to the FTC's complaint, Perrigo and Alpharma agreed to allocate to Perrigo the sale of over-the-counter store-brand children's liquid Motrin for seven years, in return for an up-front payment and a royalty on Perrigo's sales of the drug. Both parties projected that prices would rise 25% if they allocated the market. As a result of the agreement, Perrigo raised its prices to those customers who had negotiated lower prices when the two companies were competing. On August 25, 2004, the court granted final approval of settlement agreements under which Alpharma and Perrigo were required to disgorge $6.25 of illegal profits for disbursement to consumers harmed by the illegal agreement. The settlement agreements also forbid the defendants from entering into agreements not to compete where one party is the first filer of an abbreviated new drug application with the FDA.

2. **Bristol-Myers Squibb Company** (See Section I A for citation and annotation.)

3. **Biovail Corporation/Elan Corporation**, C-4057, (consent order issued August 15, 2002) (FTC Commission Actions: August 20, 2002 (www.ftc.gov)). According to the complaint, Biovail and Elan were the only companies with FDA approval to market 30 mg and 60 mg generic Adalat. Elan was the first to file for FDA approval on the 30 mg dosage, and Biovail was the first to file for FDA approval on the 60 mg dosage. Pursuant

to the Hatch-Waxman Act, Elan qualified for 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail qualified for 180 days of exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second to file on the dosage for which the other was the first filer. Prior to generic entry, Bayer's sales of the branded form of the 30 mg and 60 mg products were in excess of $270 million a year. In October 1999, Biovail and Elan entered into an agreement involving these products. In exchange for specified payments, Elan appointed Biovail as the exclusive distributor of Elan's 30 mg and 60 mg products and allowed Biovail to profit from the sale of both products. Biovail appointed Teva Pharmaceuticals, Inc. to sub-distribute Elan's 30 mg product in the United States, and agreed to appoint another firm to sub-distribute Elan's 60 mg product. The agreement had a minimum term of 15 years.

In March 2000, the FDA gave final approval to Elan's 30 mg product and Elan, under its agreement with Biovail, entered the market with its 30 mg product through Biovail. In December 2000, the FDA gave final approval to Biovail's 60 mg product and Biovail entered the market with that product. Also in December 2000, the FDA gave final approval to Biovail's 30 mg product, but Biovail never launched that product. Similarly, in October 2001, the FDA gave final approval to Elan's 60 mg product, but Elan never launched that product. Thus, Elan had a monopoly over 30 mg generic Adalat, the profits from which it shared with Biovail; Biovail had a monopoly over 60 mg generic Adalat, having paid Elan a multi-million dollar royalty; and neither launched a product in competition with the other's dosage form.

The order requires Biovail and Elan to terminate their agreement immediately, and prohibits them from entering similar agreements in the future. It requires them to use best efforts to effect independent launches of both 30 mg and both 60 mg generic Adalat products as promptly as possible, and contains an interim supply arrangement to ensure that consumers continue to have access to at least one 30 mg and one 60 mg product while Biovail and Elan unwind their agreement. In addition, the order contains strict reporting and notice requirements intended to assist the Commission in monitoring compliance with the order.

4. **Schering Plough Corporation, et. al.**, D. 9297, Complaint issued March 30, 2001, Initial Decision issued June 27, 2003, rev'd by Commission Decision and Order December 8, 2003 (FTC Commission Actions: April 2, 2001, July 2, 2002, December 18, 2003 (www.ftc.gov); rev'd 402 F.3d 1056 (11th Cir. 2005); order denying rehearing *en banc* issued May 31, 2005 (Pet. App. 36a-153a (unreported); Petition for Certiorari filed August, 2005 (FTC Commission Actions: August 29, 2005 (www.ftc.gov); Consent order as to American Home Products issued April 2, 2002 (FTC Commission Actions: April 5, 2002 (www.ftc.gov). The complaint alleged that Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products Corporation entered into anticompetitive agreements in which Schering paid Upsher and American Home Products millions of dollars to forgo launching a competitive generic alternative to K-Dur 20, an

extended-release potassium chloride supplement manufactured by Schering. Schering sued Upsher, a generic drug manufacturer, for patent infringement after Upsher sought FDA approval to manufacture and distribute Klor Con M20, a generic version of K-Dur 20. According to the complaint, Schering and Upsher reached an agreement in 1997 to settle the patent infringement lawsuit, whereby Schering paid Upsher $60 million dollars and Upshur agreed not to market any generic version of K-Dur 20 until September, 2001. Under the agreement, Schering received licenses to market five of Upsher's products but, the complaint charged, Schering paid Upsher to secure it's agreement to the 2001 entry date, and the effect of the agreement was to ensure that no other company's generic K-Dur 20 could obtain FDA approval and enter the market during the term of the agreement.

The complaint also alleged that Schering agreed to pay ESI Lederle, Inc., a division of American Home Products, to forgo marketing its generic version of K-Dur 20, in connection with settlement of patent infringement litigation. ESI agreed, in exchange for the payments, not to market any generic version of K-Dur 20 until January 2004, and to market only one generic version between January 2004 and September 2006 (when Schering's patent expired). ESI also agreed not to prepare, or help any other firm prepare, bioequivalence studies necessary for FDA approval of an application for a generic version of K-Dur 20 until September 2006. American Home Products agreed to a proposed consent agreement and on April 2, 2002, the Commission approved a final order settling the charges against American Home Products. The order prohibits American Home Products, whether acting as a brand or generic competitor, from entering into agreements in which a generic company agrees not to market its drug or enter the market with a non-infringing generic drug.

After an administrative trial as to respondents Schering and Upsher, the ALJ dismissed the complaint. In an initial decision issued on June 27, 2002, Judge Chappell ruled that Schering's payments to Upsher were solely for licenses to Upsher's products and not in exchange for agreement to the 2001 entry date. The ALJ also held that complaint counsel could not prevail absent proof that the Upsher and AHP products did not infringe Schering's patent. In addition, he found that the relevant product market was all oral potassium supplements, and that Schering did not have monopoly power in that market. Complaint counsel appealed.

On December 8, 2003, the Commission reversed the ALJ's decision. It ruled that Schering paid Upsher to delay the entry of generic competition, and not merely for the products licensed. The Commission also ruled that Schering's agreements with both Upsher and AHP were anticompetitive because Schering's payments resulted in greater protection from competition than the parties expected from continued litigation. In addition, the Commission considered it not necessary or desirable to adjudicate the merits of the underlying patent disputes in order to assess the competitive effects of the agreements.

On March 8, 2005, the Eleventh Circuit set aside the Commission decision, and vacated the cease and desist order. The Eleventh Circuit held the Commission did not establish that the challenged agreements restricted competition beyond the exclusionary effects of Schering's patent. On May 31, 2005, the Eleventh Circuit denied the Commission's petition for rehearing *en banc*. The Commission filed a petition for certiorari in August, 2005.

5. **Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp.,** D. 9293 (consent order issued May 8, 2001) (FTC Commission Actions: May 11, 2001 (www.ftc.gov)). The complaint alleged that Hoechst and Andrx entered into an agreement in which Andrx was paid millions of dollars to delay bringing to market a competitive generic alternative to Cardizem CD. Andrx, a generic drug manufacturer, was the first to file for FDA approval to market its generic version of Hoechst's brand name hypertension and angina drug, Cardizem CD, but was sued by Hoechst for patent infringement. Because of Hatch-Waxman provisions that grant the initial generic manufacturer a 180 day market exclusivity period, the complaint alleged the effect of the agreement was to ensure that no other company's generic drug could obtain FDA approval and enter the market during the term of the agreement. Under the agreement, according to the complaint, Andrx agreed not to market its product when it received FDA approval, not to give up or relinquish its 180-day exclusivity right, and not to market a non-infringing generic version of Cardizem CD during the ongoing patent litigation. The order prohibits respondents from entering into agreements in which the first generic company to file an ANDA agrees: 1) not to relinquish its rights to the 180-day exclusivity period; and 2) not to develop or market a non-infringing generic drug product. The order also requires Hoechst and Andrx to notify the Commission, and obtain court approval, before entering into any agreements involving payments to a generic company in which the generic company temporarily refrains from bringing a generic drug to market.

6. **Abbott Laboratories and Geneva Pharmaceuticals, Inc.**, C-3945, C-3946 (consent orders issued May 22, 2000) (FTC Commission Actions: May 26, 2000 (www.ftc.gov)). The complaint alleged that Abbott paid Geneva $4.5 million per month to delay bringing to market a generic alternative to Abbott's brand-name hypertension and prostate drug, Hytrin. Geneva, a generic drug manufacturer, sought and received FDA approval to market its generic capsule version. After Geneva received FDA approval, Abbott and Geneva reached an agreement whereby Geneva would not bring a generic version of Hytrin to market during the ongoing patent litigation on Geneva's tablet version of Hytrin in exchange for the $4.5 million monthly payment, an amount which exceeded the amount Abbott estimated Geneva would have received if it actually marketed the generic drug. Because of Hatch-Waxman provisions that grant the initial generic manufacturer a 180-day market exclusivity period, the complaint alleged the effect of the agreement was to ensure that no other company's generic Hytrin could obtain FDA approval and enter the market during the term of the agreement. The consent orders prohibit Abbott and Geneva from entering into agreements in which a generic company agrees with the brand drug manufacturer to 1) give up or transfer its Hatch-Waxman 180-day exclusivity rights,

or 2) not enter the market with a non-infringing product. In addition, the orders require that agreements involving payments to a generic company to stay off the market during the pendency of patent litigation be approved by the court with notice to the Commission. Geneva was also required to waive its right to a 180-day exclusivity period for its generic tablet, so other generic tablets could immediately enter the market. In a statement accompanying the consent orders, the Commission warned that in the future it will consider its entire range of remedies in enforcement actions against similar arrangements, including seeking disgorgement of illegally obtained profits.

C. Agreements on Price or Price-Related Terms

1. **Asociacion de Farmacias Region de Arecibo**, 127 F.T.C. 266 (1999) (consent order). The complaint alleged that an association, composed of approximately 125 pharmacies in northern Puerto Rico, fixed the terms and conditions, including fixing prices, of dealing with third party payers, and threatened to withhold services from a government program to provide health care services for indigent patients. The association was formed in 1994 as a vehicle to negotiate with health plans. According to the complaint, in January 1995, the association refused to contract with Triple-S, the payer for the reform program in northern Puerto Rico, until Triple-S raised the fees paid to the association's members. Furthermore, in March 1996, the association threatened to withhold its members' services unless Triple-S rescinded a new fee schedule calling for lower reimbursement fees for the pharmacies. Triple-S acceded to the association's demands and increased fees by 22%. The order prohibits the association from negotiating on behalf of any pharmacies with any payer or provider, jointly boycotting or refusing to deal with third party payers, restricting the ability of pharmacies to deal with payers individually, or determining the terms or conditions for dealing with third party payers.

2. **Mylan Laboratories et al.**, 62 F. Supp. 2d 25 (D.D.C. 1999) (FTC Commission Actions: November 29, 2000 (www.ftc.gov)). In a complaint seeking injunctive and other relief filed in U.S. District Court for the District of Columbia, the Commission charged Mylan Laboratories and three other companies, Profarmaco S.R.L., Cambrex Corporation, and Gyma Laboratories, with restraint of trade and conspiracy to monopolize the markets for two generic anti-anxiety drugs, lorazepam and clorazepate. The complaint also charged Mylan with monopolization and attempted monopolization of those markets. Thirty four state Attorneys General filed a similar complaint in U.S. District Court. According to the FTC's complaint, Mylan, the nation's second largest generic drug manufacturer, sought to restrain competition through exclusive licensing arrangements for the supply of the raw material necessary to produce the lorazepam and clorazepate tablets, thereby allowing Mylan to dramatically increase the price of lorazepam and clorazepate tablets. On July 7, 1999, the court denied defendants' motions to dismiss the FTC complaint, finding that § 13(b) of the FTC Act allows the Commission to seek permanent injunctive relief for violations of "any provision of law" enforced by the FTC, and allows the Commission to seek monetary remedies such as the disgorgement of profits. On November 29, 2000, the Commission approved a proposed settlement, subject to approval by the federal district

court, under which Mylan agreed to pay $100 million for distribution to injured consumers and state agencies. The defendants also agreed to an injunction barring them from entering into similar unlawful conduct in the future. Fifty states and the District of Columbia also approved the agreement. In a separate statement, Commissioner Leary dissented regarding the financial aspects of the settlement because of his concern that it sets an undesirable precedent for use of the Section 13(b) remedy in federal and state antitrust enforcement, and conflicts with the holding in Illinois Brick concerning the ability of indirect purchasers to claim damages. In a separate statement, Commissioners Pitofsky, Anthony, and Thompson agreed with the need to use discretion in seeking disgorgement in future antitrust cases, but stated that the decision to seek disgorgement in this case was appropriate and consistent with policy considerations towards indirect purchasers raised by Illinois Brick. On February 9, 2001, the court entered the Stipulated Permanent Injunction agreed to by the parties. On February 1, 2002, the court granted final approval of the settlement agreement and distribution plan under which Mylan was required to place $100 million into an escrow account for disbursement to purchasers of lorazepam and/or clorazepate during the time period covered by the settlement.

3. **Institutional Pharmacy Network**, 126 F.T.C. 138 (1998) (consent order). The complaint alleged that five institutional pharmacies unlawfully fixed prices and restrained competition among institutional pharmacies in Oregon, leading to higher reimbursement levels for serving Medicaid patients in Oregon long-term care institutions. The five pharmacies, Evergreen Pharmaceutical, Inc., NCS Healthcare of Oregon, Inc., NCS Healthcare of Washington, Inc., United Professional Companies, Inc., and White, Mack and Wart, Inc. (which provide institutional pharmacy services for 80% of those patients in Oregon receiving such services) competed to provide prescription drugs and services to long term care institutions. According to the complaint, the pharmacies formed IPN to offer their services collectively and maximize their leverage in bargaining over reimbursement rates, but did not share risk or provide new or efficient services. The order prohibits IPN and the institutional pharmacy respondents from entering into similar price fixing arrangements.

4. **RxCare of Tennessee, Inc. et al.**, 121 F.T.C. 762 (1996) (consent order). The complaint charged that RxCare of Tennessee, a leading provider of pharmacy network services in that state, used a "most favored nation" clause (MFN) in order to discourage pharmacies from discounting, and to limit price competition among pharmacies in their dealings with pharmacy benefits managers and third-party payers. The MFN clause at issue required that if a pharmacy in the RxCare network accepted a reimbursement rate from any other third-party payer that is lower than the RxCare rate, the pharmacy must accept that lower rate for all RxCare business in which it participates. Combined with RxCare's market power (the network included 95% of all chain and independent pharmacies in Tennessee), the complaint alleged that the MFN clause forced some pharmacies in the network to reject lower reimbursement rates for prescriptions they fill for patients covered by other health plans. The order bars RxCare from including the MFN clause in its pharmacy agreements.

5. **Baltimore Metropolitan Pharmaceutical Association, Inc. and Maryland Pharmacists Association**, 117 F.T.C. 95 (1994) (consent order). The complaint alleged that the Maryland Pharmacists Association (MPhA) and the Baltimore Metropolitan Pharmaceutical Association (BMPA), in response to cost-containment measures initiated by the Baltimore city government employees' prescription-drug plan, illegally conspired to boycott the plan in order to force higher reimbursement rates for prescriptions. According to the complaint, the associations' actions increased the cost of obtaining drugs through prescription drug plans, and reduced price competition between the firms providing these prescriptions. Under the consent order, MPhA and BMPA are prohibited from entering into, organizing, or encouraging any agreement between or among pharmacy firms to refuse to enter into, or to withdraw from, any participation agreement offered by a third-party payer. In addition, for five years, the associations are prohibited from providing comments or advice to any pharmacist or pharmacy concerning participation in any existing or proposed participation agreement, or the intention of other pharmacists or pharmacies to withdraw from or join a participation agreement. The associations are also prohibited from continuing meetings if two persons make statements concerning their firms' intentions to join a participation agreement.

6. **Southeast Colorado Pharmacal Association**, 116 F.T.C. 51 (1993) (consent order). The complaint alleged that the Southeast Colorado Pharmacal Association (SCPhA) illegally conspired to boycott a prescription drug program offered through a state-retirees health plan in an attempt to force the program to increase its reimbursement rate for prescriptions filled by its pharmacy members. The order prohibits the association from entering into or threatening to enter into any agreement with pharmacies to withdraw or refuse to participate in similar reimbursement programs in the future. In addition, for five years, SCPhA is prohibited from providing comments or advice to any pharmacist or pharmacy concerning participation in any existing or proposed participation agreement, communicating the intention of other pharmacists or pharmacies to withdraw from or join a participation agreement, or soliciting other pharmacy firms' intentions about entering into a participation agreement. The association is also prohibited from continuing meetings of pharmacy representatives if members make statements concerning their firms' intentions to join a participation agreement.

7. **Chain Pharmacy Association of New York State, Inc.**, 114 F.T.C. 327 (1991) (consent order). The complaint charged that the Chain Pharmacy Association (Chain) and its members conspired to boycott the New York State Employees Prescription Plan, in order to force an increase in reimbursement rates for plan participants who provide prescriptions to state employees. The complaint alleged that the collective refusal to participate in the program injured consumers in New York by reducing competition among pharmacy firms with respect to third-party prescription plans. The order prohibits Chain from organizing or entering into any agreement among pharmacy firms to withdraw from or refuse to enter into third-party payer prescription drug plans. Also, for a period of ten years, the order prohibits Chain from communicating to any pharmacist or pharmacy firm information regarding any other pharmacy firm's intentions to enter or

refuse to enter into such a participation agreement, or from continuing meetings of pharmacy firm representatives if two persons make statements concerning their firms' intentions to join a participation agreement. For a period of eight years, the order prohibits Chain from advising another pharmacy firm on whether to enter into any payer participation agreement. See Pharmaceutical Society of the State of New York, Inc. (discussed below).

8. **Peterson Drug Company of North Chili, New York, Inc.**, 115 F.T.C. 492 (1992) (consent order). As a member firm of Chain Pharmacy Association, Peterson Drug Company of North Chili, New York, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. After Peterson failed to appeal an Administrative Law Judge's decision in favor of complaint counsel, the Commission adopted the initial decision and entered an order similar to the Chain Pharmacy order (discussed above).

9. **Fay's Drug Company, Inc.**, 114 F.T.C. 171 (1991) (consent order). As a member firm of Chain Pharmacy Association, Fay's Drug Company, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

10. **Kinney Drugs, Inc.**, 114 F.T.C. 367 (1991) (consent order). As a member firm of Chain Pharmacy Association, Kinney Drugs, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

11. **Melville Corporation**, 114 F.T.C. 171 (1991) (consent order). As a member firm of Chain Pharmacy Association, Melville Corporation was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

12. **Rite Aid Corporation**, 114 F.T.C. 182 (1991) (consent order). As a member firm of Chain Pharmacy Association, Rite Aid Corporation was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

13. **James E. Krahulec**, 114 F.T.C. 372 (1991) (consent order). As a member firm of Chain Pharmacy Association, James E. Krahulec, along with Rite Aid and the members of Chain Pharmacy Association, was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

14. **Pharmaceutical Society of the State of New York, Inc.**, 113 F.T.C. 661 (1990) (consent order). The complaint charged that the Pharmaceutical Society of the State of New York, Inc. (PSSNY) conspired to boycott the New York State Employees Prescription Plan, in order to force an increase in reimbursement rates for plan participants who provide prescription drugs to state employees. According to the complaint, the society's actions reduced price competition, forced the state to pay substantial additional sums for prescription drugs, and coerced the state into raising the prices paid to pharmacies under the state plan. Under the consent order, the society agreed not to enter into any agreement between pharmacy firms to withdraw from or refuse to enter into any participation agreement. Also, for a period of ten years, the order prohibits PSSNY from continuing meetings if two persons make statements concerning their firms' intentions to join a participation agreement; and requires PSSNY to refrain from communicating to any pharmacist or pharmacy firm any information regarding any other pharmacy firm's intentions to enter or refuse to enter into such a participation agreement. For a period of eight years, the order prohibits PSSNY from providing comments or advice to any pharmacist or pharmacy on the desirability of participating in any existing or proposed participation agreement. *See* Chain Pharmacy Association (discussed above).

15. **Empire State Pharmaceutical Society, Inc.**, 114 F.T.C. 152 (1991) (consent order). An affiliate of Long Island Pharmaceutical Society, Empire State Pharmaceutical Society was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.

16. **Capital Area Pharmaceutical Society**, 114 F.T.C. 159 (1991) (consent order). An affiliate of PSSNY, Capital Area Pharmaceutical Society was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.

17. **Alan Kadish**, 114 F.T.C. 167 (1991) (consent order). As president of PSSNY, Alan Kadish was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.

18. **Long Island Pharmaceutical Society, Inc.**, 113 F.T.C. 669 (1990) (consent order). An affiliate of PSSNY, Long Island Pharmaceutical Society, Inc. was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.

19. **Pharmaceutical Society of Orange County, Inc.**, 113 F.T.C. 645 (1990) (consent order). An affiliate of PSSNY, Pharmaceutical Society of Orange County, Inc. was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was

entered.

20. **Westchester County Pharmaceutical Society, Inc.**, 113 F.T.C. 159 (1990) (consent order). An affiliate of PSSNY, Westchester County Pharmaceutical Society, Inc. was charged with conspiracy to boycott the New York State Employees Prescription Plan along with PSSNY. A separate order similar to the PSSNY order (discussed above) was entered.

21. **Brooks Drug, Inc.**, 112 F.T.C. 28 (1989) (consent order). As a member firm of Chain Pharmacy Association, Brooks Drug Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

22. **Carl's Drug Co., Inc.**, 112 F.T.C. 15 (1989) (consent order). As a member firm of Chain Pharmacy Association, Carl's Drug Co., Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

23. **Genovese Drug Stores, Inc.**, 112 F.T.C. 23 (1989) (consent order). As a member firm of Chain Pharmacy Association, Genovese Drug Stores, Inc. was charged with conspiracy to restrain trade in its refusal to participate in the New York State Employees Prescription Plan. A separate order similar to the Chain Pharmacy order (discussed above) was entered.

D. Agreements to Obstruct Innovative Forms of Health Care Delivery or Financing

1. **Asociacion de Farmacias Region de Arecibo** (See Section II B for citation and annotation.)

E. Illegal Tying and Other Arrangements

1. **Sandoz Pharmaceuticals Corporation**, 115 F.T.C. 625 (1992) (consent order). The complaint charged that Sandoz unlawfully required those who purchased its schizophrenia drug, clozapine (the first new drug for the treatment of schizophrenia in more than 20 years), to also purchase distribution and patient-monitoring services from Sandoz. Blood monitoring of patients taking clozapine is required to detect a serious blood disorder caused by the drug in a small percentage of patients. The complaint alleged that this illegal "tying" arrangement raised the price of clozapine treatment and prevented others – such as private laboratories, the Veterans Administration, and state and local hospitals – from providing the related blood tests and necessary patient monitoring. The order prohibits Sandoz from requiring any purchaser of clozapine, or a patient taking clozapine, to buy other goods or services from Sandoz. The order guards

against the possibility that Sandoz might restrict other firms that want to market generic clozapine in the United States after Sandoz's exclusive selling right expires in 1994, by requiring Sandoz to provide information on reasonable terms if any company is in need of information about patients who have had adverse reactions to the drug. The order also requires Sandoz to not unreasonably withhold information from researchers studying the medical aspects of clozapine use.

III. PHARMACEUTICAL MERGERS

A. Horizontal Mergers between Direct Competitors

Novartis AG, C-4150 (consent order issued September 21, 2005) (FTC Commission Actions: September 23, 2005 (www.ftc.gov)). The complaint alleged that Novartis AG's acquisition of EON Labs would lessen competition and result in higher prices in the markets for three generic drugs. According to the complaint, the generic forms of these drugs constituted the appropriate product market under which to analyze the merger because the branded drug did not effect the pricing of the generic. Novartis and Eon were significant competitors in the markets for generic desipramine hydrochloride tablets (a tricyclic antidepressant), generic orphenadrine citrate ER tablets (a muscle relaxant), and generic rifampin oral capsules (used in the treatment of tuberculosis):

Generic desipramine hydrochloride tablets. Prior to the acquisition, only Novartis and Eon marketed all six strengths of generic desipramine hydrochloride tablets in the U.S. The sole other competitor, Watson Pharmaceuticals, marketed only three of the six strengths. After the acquisition, Novartis would account for more than 95% of all generic desipramine hydrochloride tablets sold in the U.S. The order requires the divestiture of Eon's desipramine hydrochloride assets to Amide. The order also requires Novartis to enter into a supply agreement with Amide until Amide gains FDA approval to manufacture the drugs on its own.

Generic orphenadrine citrate ER tablets. Prior to the acquisition, Novartis, Eon, and Impax manufactured and marketed generic orphenadrine citrate ER tablets in the U.S. After the acquisition Novartis would account for 70% of U.S. sales. The proposed order requires the divestiture of Novartis' orphenadrine citrate ER tablets to Amide. The order also requires Novartis to enter into a supply agreement with Amide until Amide gains FDA approval to manufacture the drugs on its own.

Generic rifampin oral capsules. Novartis, Eon, and VersaPharm manufactured and marketed generic *rifampin oral capsules* in the U.S. After the acquisition Novartis would account for 70% of U.S. sales. The order requires the divestiture of Novartis' generic rifampin oral capsules assets to Amide, which currently contract manufactures rifampin for Novartis.

2. **Genzyme Corporation and Ilex Oncology**, C-4128 (consent order issued January 31, 2005 (FTC Commission Actions: February 4, 2005 (www.ftc.gov)). The complaint alleged that the merger of Genzyme and Ilex eliminated competition in the market for immunosuppressant drugs used in solid organ transplants (SOT). SOT acute therapy drugs are used in solid organ transplants to suppress the transplant recipient's immune system. Genzyme, the leading supplier of SOT acute therapy drugs, marketed Thymoglobulin. Ilex's Campath, a new entrant into the market, was an especially close competitor to Thymoglobulin due to its similar mechanisms of action. According to the complaint the other four immunosuppressant drugs on the market were not substitutes for Genzyme's and Ilex's SOT acute therapy drugs because of different mechanisms of action. The order requires Genzyme to divest its contractual and decision making rights, including its portion of the earnings from sales of Campath, to Schering, which already markets and distributes Campath in the U.S. The order also appointed a monitor to oversee the divestiture of Campath earnings from solid organ transplant sales.

3. **Sanofi-Synt and Aventis**, C-4112 (consent order issued September 20, 2004) (FTC Commission Actions: September 24, 2004 (www.ftc.gov)). The complaint alleged that the merger of two large French pharmaceutical companies would lessen competition in three pharmaceutical markets in the United States and increase the likelihood that consumers would be forced to pay higher prices:

   # *Factor Xa Inhibitors.* Factor Xa inhibitors are anticoagulent products used to treat conditions related to excessive blood clot formation. Sanofi and Aventis were the only two companies positioned to successfully compete in the market for factor Xa inhibitors. Lovenox, manufactured by Aventis, accounted for 92% of factor Xa inhibitor sales in the U.S. Sanofi manufactured Arixtra, a recent entrant to the market. The order requires that Sanofi: 1) divest Arixtra to Glaxo, 2) transfer manufacturing facilities used to produce Arixtra to Glaxo, 3) contract manufacture certain ingredients until Glaxo can obtain the necessary regulatory approvals and supply sources to make the ingredients, and 4) help Glaxo complete three clinical trials.

   # *Cytotoxic Colorectal Cancer Drugs*. Cytotoxic drugs are used in the treatment of colorectal cancer. Sanofi's Eloxatin and Camptosar (irinotecan), which was manufactured by Yakult Honsha and marketed in the U.S. by Pfizer, accounted for over 80% of the U.S. market. Aventis did not market a similar drug in the U.S., but licensed irinotecan under the brand name Campto from Yakult for sale in other territories. In addition, through contractual relationships with Pfizer, Aventis shared the results of key clinical trials with Pfizer, and possessed a number of U.S. patents relating to Camptosaur. According to the complaint, the merger gave Sanofi access to Camptosar's pricing, forecasts, and marketing strategy, which would result in diluted competition between Sanofi and Pfizer. The order includes provisions that require the parties to divest to Pfizer key clinical studies for Campto that Aventis is currently conducting, certain U.S.

patents, and other assets related to areas where Pfizer markets Camptosar.

Prescription Insomnia Treatments. Sanofi's Ambien accounted for over 85% of the U.S. market for prescription insomnia treatments. Sepracor planned to enter this market within nine months as a competitor to Sanofi with its product Estorra, which is licensed to Sepracor from Aventis. Under the licensing agreement, Aventis is entitled to royalty payments based on Estorra sales. After the acquisition Sanofi would control the leading product in the market and have a financial stake in what is likely to be its main competitor. The order requires the parties to divest Aventis'contractual rights to Estorra, either to Sepracor or a third party approved by the FTC.

4. **Pfizer Inc. and Pharmacia Corporation,** C-4075 (consent order issued May 30, 2003) (FTC Commission Actions: May 30, 2003 (www.ftc.gov)). The complaint alleged that Pfizer's $60 billion acquisition of Pharmacia would lessen direct or potential competition between the two companies in nine highly concentrated markets, and result in the delay or elimination of additional price competition or higher prices for consumers:

Extended Release Treatments for Overactive Bladder (OAB). Pharmacia's Detrol and Detrol LA and Johnson & Johnson's Ditropan XL were the only two extended release OAB products marketed in the U.S. Pfizer, one of two companies best-positioned to enter the market within the next two years, was in the process of seeking FDA approval for darifenacin, its extended release OAB product. The complaint alleged that the merger would eliminate potential competition between Pharmacia and Pfizer and increase the likelihood that Pfizer would delay the launch of darifenacin. The order requires Pfizer to divest darifenacin and certain other assets to Novartis AG and contains other provisions to ensure that the divestiture is successful;

Combination Hormone Replacement Therapies (HRT). Pfizer's femhrt and Pharmacia's Activella were two of the three leading combination HRT products marketed in the U.S. After the merger, Pfizer and Wyeth, the other leading competitor, would control approximately 94% of the HRT market. The order requires the divestiture of Pfizer's femhrt to Galen Holdings plc, and contains other provisions to ensure that the divestiture is successful;

Treatments for Erectile Disfunction (ED). With over 95% of the U.S. ED market and a second generation Viagra-like product in development, Pfizer dominated the research, development, manufacture and sales of prescription drugs for ED. Pharmacia, Pfizer's only significant potential competitor, had two products, IN APO and PNU-142,774, in clinical development. The order requires Pharmacia to return all of its rights for IN APO to Nastech Pharmaceutical Company, and to divest all of its rights and interests for the field of human sexual for PNU-142,774 to Neurocrine Biosciences, Inc. The proposed order also contains other provisions

to ensure that the divestiture is successful;

Drugs for Canine Arthritis. Three companies sold prescription drugs for the treatment of canine arthritis: Pfizer's product, Rimadyl, accounted for 70% of the market and Wyeth's product, EtoGesic, accounted for 30% of the market. Novartis began marketing Deramaxx in early 2003 under a licensing agreement with Pharmacia, which currently manufactured Deramaxx, and supplied it to Novartis. The complaint alleged that because of its license and supply agreement with Novartis, Pfizer, the leading competitor in the market, would control the manufacturing and supply of the competing product Deramaxx, and under the existing licensing agreement, have access to Novartis' sensitive confidential information on Deramaxx' pricing, forecasts, and marketing strategy. The order requires Pharmacia to renegotiate its license and supply agreement with Novartis to allow Novartis to operate as an independent competitor by eliminating the control Pfizer would have over Novartis's product, restricting the type of information Pfizer would be able to obtain about Deramaxx, and allowing Novartis to compete with Pfizer in the development of a second generation canine arthritis product;

Antibiotic Treatments for Lactating Cow Mastitis and Dry Cow Mastitis. Pfizer, Pharmacia and Wyeth were the only significant competitors in the markets for lactating cow and dry cow mastitis antibiotic products. After the merger Pfizer and Pharmacia would account for 50% of the sales of lactating cow mastitis products and 55% of the sales of dry cow mastitis products. The order requires Pfizer to divest all of its U.S. rights to its bovine mastitis antibiotic products to Schering-Plough Corporation;

Over-the-Counter Hydrocortisone Creams and Ointments. Pfizer's Cortizone brand and Pharmacia's Cortaid brand were the only two branded hydrocotisone creams on the U.S. market, and accounted for 55% of the over-the-counter sales of hydrocortisone creams and ointments. The order requires Pharmacia to divest its Cortaid business to Johnson and Johnson;

Over-the-Counter Motion Sickness Medications. Pfizer, with its Bonine product and Pharmacia, with its Dramamine product were the two leading suppliers in this market and accounted for a combined market share of 77%. The order requires Pfizer to divest its U.S. and Puerto Rican Bonine assets to Insight Pharmaceuticals Corporation; and

Over-the Counter Cough Drops. Pfizer, with its Halls brand and Pharmacia, with its Ludens brand, were the only two significant competitors in the over-the-counter cough drops market. The order requires Pfizer to divest its Halls cough drop business to Cadbury Schweppes.

The Commission also appointed an interim monitor to oversee the asset transfer and to ensure that Pfizer and Pharmacia comply with all of the provisions of the order.

5. **Baxter International Inc. and Wyeth Corporation**, C-4068, (consent order issued February 3, 2003) (FTC Commission Actions: February 7, 2003 (www.ftc.gov)). The Commission's complaint charged that Baxter's acquisition of the generic injectable drug business from Wyeth's subsidiary, ESI Lederle, would reduce either current horizontal competition or potential competition in the market for five injectable drugs:

   # *Propofol* Baxter, under a supply agreement with GensiaSicor, marketed the only generic version of AstraZeneca's branded propofol Diprivan, an anesthetic preferred for outpatient surgery because of its short duration profile. Wyeth was in the process of seeking FDA approval and was one of two companies most likely to enter the market with its own generic version. The complaint alleged that new entry would be difficult and lengthy. Among other things, the preservatives used in the Baxter marketed propofol and in AstraZeneca's product are patent protected and the manufacturing process complex. In order to preserve the future competition and probable lower prices in the market that would have resulted from the entry of a Wyeth generic propofol, the order required the divestiture of Wyeth's propofol business to Faulding Pharmaceutical Company, as well as other requirements to ensure the success of the divestiture;

   # *Pancuronium* In the market for pancuronium, a long-acting neuromuscular blocking agent used to freeze muscles during surgery and for patients who are mechanically ventilated, Baxter (under an exclusive marketing agreement with GensiaSicor), along with Wyeth, and Abbott were the only suppliers. The complaint alleged that the acquisition would have reduced the number of competitors from three to two, leaving Baxter and Wyeth with a combined market share of 74% after the acquisition. New entry was unlikely because pancuronium was an older drug with limited usage. The order required Baxter to divest its pancuronium assets to GenesiaSicor;

   # *Vecuronium* Wyeth discontinued its production of vecuronium, an intermediate-acting neuromuscular blocking agent used during surgery or ventilation, in 2001, but planned to re-launch the product. Prior to stopping production, Baxter (under an exclusive supply agreement with GensiaSicor) and Wyeth were the two largest of five vecuronium suppliers and held a 53% combined market share. The complaint charged that the acquisition would eliminate the price competition that would have resulted when Wyeth re-entered the market. The order requires Baxter to divest its vecuronium assets to GenesiaSicor;

   # *Metoclopramide* The acquisition would have combined two of four companies supplying metoclopramide, an antiemetic used in certain types of chemotherapy and other post-operative treatments. Wyeth, manufacturer of the branded version

of metoclopramide, and Baxter, the exclusive supplier of GensiaSicor's generic metoclopramide drug, together accounted for over half of the U.S. market. The order requires Baxter to terminate its interests in and divest its assets to GensiaSicor;

New Injectable Iron Replacement Therapies (NIIRTs) The complaint alleged harm to potential competition and/or price competition in the market for NIRTs, including both iron gluconate and iron sucrose, which are used to treat iron deficiency in hemodialysis patients. Baxter and Watson jointly marketed Ferrlecit, one of only two NIIRT's approved for sale in the U.S. Wyeth was the best positioned firm to successfully enter the market. The complaint charged that entry was difficult and lengthy. Among other things, a lack of raw material suppliers and complex manufacturing processes complicate entry. The order requires Baxter to terminate its co-marketing agreement with Watson and provides incentives for Baxter to proceed with development of Wyeth's iron gluconate product.

The Commission also appointed a monitor to ensure Baxter's and Wyeth's compliance with the order.

6. **Amgen Inc. and Immunex Corporation**, C-4956, (consent order issued September 3, 2002) (FTC Commission Actions: September 6, 2002 (www.ftc.gov)). The complaint alleged that Amgen's $16 billion acquisition of Immunex would lessen direct or potential competition in three highly concentrated biopharmaceutical markets:

Neutrophil Regeneration Factors Amgen's Neupogen and Neulasta and Immunex's Leukine were the only neutrophil regeneration factors approved by the FDA for sale in the U.S. Neutrophil regeneration factors are used to help the immune systems of chemotherapy patients by increasing the production of two types of white blood cells. The order requires that Immunex divest its Leukine product to Schering AG;

TNF Inhibitors TNF inhibitors are used to treat inflamation in patients having autoimmune diseases by preventing the binding of TNF (a cytokine that promotes inflamation) receptors and proteins. Immunex was one of two companies that marketed TNF inhibitors in the U.S. Amgen, one of three companies that had TNF inhibitors in clinical development for sale in the U.S., planned to launch its product in 2005. The order requires that Amgen license certain patents to Sereno, a Swiss company developing a TNF inhibitor for use in Europe, that block Sereno's ability to market in the U.S.;

IL-1 Inhibitors IL-1 inhibitors are also used to treat inflamation in patients with autoimmune diseases. Amgen manufactured the only IL-1 inhibitor on the market in the U.S. Immunex and Regeneron were the only companies with IL-1

inhibitors in clinical trials; Immunex, however, held several patents that could delay or stop the development and marketing of Regeneron's IL-1 inhibitor. The order requires that Immunex license certain patents to Regeneron that will allow it to develop and bring its product to market.

7. **The Hearst Trust, et. al.**, Civil Action No. 1:01CV00734 (D.D.C. filed April 5, 2001); Civil Action No. 1:01CV02119 (D.D.C. filed October 11, 2001) (civil penalty action); (FTC Commission Actions: October 11, December 14, 2001, January 9, 2002 (www.ftc.gov)). In a complaint filed in U.S. District Court for the District of Columbia, the Commission charged Hearst and its wholly owned subsidiary, First DataBank Inc., with illegally acquiring a monopoly in the market for electronic integratable drug information databases, in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. According to the complaint, the 1998 acquisition of Medi-Span, Inc. allowed First DataBank to institute substantial price increases to its customers for use of the electronic databases which contain clinical, pricing and other information on prescription and non-prescription drugs. The complaint also charged Hearst with violating Section 7A (a) of the Clayton Act, by illegally withholding certain 4(c) documents about the Medi-Span acquisition that were required for pre-merger notification review under the Hart-Scott-Rodino Act. The complaint asked the Court to order Hearst to create and divest a new competitor to replace Medi-Span, and to disgorge the illegally gained profits from the anticompetitive price increases. On December 14, 2001, the Commission voted to approve a proposed settlement that required Hearst to divest the former Medi-Span to Facts and Comparisons and to pay $19 million in disgorgement of illegal profits to its customers. Commissioners Leary and Swindle issued dissenting statements concerning the disgorgement portion of the order. The district court approved the final order and stipulated permanent injunction on December 18, 2001. The Commission also asked the Department of Justice to file a separate complaint in U.S. District Court seeking civil penalties for Hearst's failure to comply with pre-merger notification reporting requirements. In a final judgment filed on October 11, 2001, Hearst agreed to pay $4 million in civil penalties. On January 9, 2002, the Commission filed a brief as intervenor opposing the private class plaintiffs' petition for an award of $5 million in attorney fees which represented 22% of the total direct purchaser settlement payment of $24 million. The Commission argued that private counsels' fees should be reduced to reflect the minimal legal work and limited incremental value that the private attorneys contributed to the settlement after the Commission had reached a tentative settlement with the parties of $16 million. On May 21, 2002, the District court ruled that the private attorneys were only entitled to a percentage of the settlement attributable to their efforts in the litigation and reduced their award to $2.4 million.

8. **Glaxo Wellcome plc and Smith Kline Beecham plc**, C-3990 (consent order issued January 26, 2001) (FTC Commission Actions: January 23, 30, 2001 (www.ftc.gov)). The Commission's complaint charged that the merger of Glaxo Wellcome (Glaxo) and SmithKline Beecham (SB) would create the world's largest research-based

pharmaceutical manufacturer, substantially lessen competition in nine separate pharmaceutical markets, and result in fewer consumer choices, higher prices and less innovation. In six markets the order required divestiture:

5HT-3 Antiemetic Drugs Glaxo and SB accounted for 90% of the sales of new generation drugs used in chemotherapy to reduce the incidence of side effects. The order required the divestiture of the worldwide rights of SB's drug Kytril to F. Hoffman LaRoche;

Injectable Antibiotic Ceftazidime Glaxo and SB were the only two manufacturers of ceftazidime, and Glaxo was the largest of three firms marketing ceftazidime. The order required the divestiture of SB's U.S. rights to manufacture and market ceftazidime to Abbott Laboratories;

Oral and Antiviral Drugs for the Treatment of Herpes, Chicken Pox and Shingles Glaxo's Valtrex and SB's Famvir were the only second-generation antiviral prescription drugs available on the market, and no other companies have similar products in development. The order required the divestiture of SB's antiviral drug Famvir to Novartis;

Topical Antiviral Drugs for the Treatment of Herpes Cold Sores SB's Denavir was the only FDA approved prescription topical antiviral drug sold in the US, and Glaxo, the only potential entrant into the market, was seeking FDA approval to market its European antiviral Zovirex in the U.S. The order required SB to divest Denavir to Novartis;

Prophylactic Vaccines for the Treatment of Herpes Glaxo and SB were the leading two of only a few firms pursuing the development of a preventative vaccine. The order required Glaxo to return to its British collaborator, Cantab Pharmaceuticals, all rights to its technology for the development of a prophylactic herpes vaccine; and

Over-the Counter H-2 Blocker Acid Relief Products Glaxo's Zantac 75 and SB's Tagamet were two of the four branded OTC H-2 acid blockers on the market. The order required the divestiture of Glaxo's U.S. and Canadian Zantac trademark rights to Pfizer.

In three markets the order addressed competitive overlaps with other research and development firms where the merger was likely to result in delay, termination, or failure to develop as a competitor:

Topoisomerase I Inhibitor Drugs Used to Treat Certain Tumors SB's Hycamptin was a second line therapy for non-small cell lung cancers and SB was developing a first line therapy for colorectal and other solid-tumor cancers. Glaxo, through a

collaboration with Gilead Sciences, was developing a drug, GI147211C, which would have been in direct competition with SB's Hycamptin. Only one other company manufactured similar anti tumor drugs. The order required Glaxo to assign all of its relevant intellectual property rights and relinquish all of Glaxo's reversionary rights to GI147211C to Gilead Sciences;

Migraine Headache Treatment Drugs Glaxo's Immitrex and Amerge were the leading sellers of triptan drugs for the treatment of migraine headache. SB had an interest in another triptan drug, frovatriptan, which was being developed and scheduled for launch by Vernalis Ltd. in the second half of 2001. The order required SB to assign all of its intellectual property rights and relinquish all options to regain control over frovatriptan to Vernalis Ltd; and

Drugs to Treat Irritable Bowel Syndrome Glaxo owned and was conducting clinical trials on Lotronex, which had been taken off the market because of possible side effects. SB had an option to acquire and market renzapride which was being developed by the British firm Alizyme Therapeutics plc. Because the merger would eliminate one of the few efforts underway to develop a drug for the treatment of irritable bowel syndrome, the order required SB to assign all of its intellectual property rights and relinquish all options to regain control over renzapride to Alizyme.

After the Commission issued the proposed consent agreement, the Commission continued to investigate the potential effects of the merger in the smoking cessation products market where Glaxo sold the prescription drug Zyban, and SB marketed Nicoderm and Nicorette, two over-the-counter nicotine replacement products. On January 23, 2001, the Commission closed the smoking cessation products investigation.

9. **Pfizer Inc. and Warner-Lambert Company**, C-3957 (consent order issued July 27, 2000) (FTC Commission Actions: July 28, 2000 (www.ftc.gov)). The complaint alleged that Pfizer's acquisition of Warner-Lambert Company would lessen competition in four pharmaceutical markets:

Antidepressant Drugs Called Selective Serotonin Reuptake Inhibitors (SSRIs) and Selective Norepinephrine Reuptake Inhibitors (SNRIs) Pfizer manufactured Zoloft, the second largest selling SSRI, and Warner and Forest Laboratories co-promoted Celexa, the fastest-growing SSRI. The order required Warner to end its co-promotion agreement with Forest, return all confidential information regarding Celexa to Forest, maintain the confidentiality of all Celexa marketing information, and prohibited former Warner sales employees involved in marketing Celexa from selling Zoloft until March 2001;

Pediculicides or Treatments for Head Lice Infestation Pfizer and Warner were the two largest manufacturers and accounted for approximately 60% of the

market. The order required Pfizer to divest its brand RID to Bayer Corporation;

Drugs for Treating Alzheimer's Disease Pfizer's Aricept and Warner's Cognex were the only two drugs sold in the U.S. for the treatment of Alzheimer's disease. The order required the divestiture of Cognex to First Horizon; and

EGFr-tk Inhibitors (drugs used to treat solid tumor cancers) Pfizer and Warner were the two most advanced among four companies developing EGFr-tk inhibitors. The order required Pfizer to return its EGFr-tk inhibitor, CP-358,774, along with its technology and knowhow assets to its development partner OSI, to grant OSI an irrevocable worldwide license to its rights and patents jointly owned with Pfizer, to provide OSI with a manufacturing and supply agreement for the continued supply of CP-358,774 until the transfer of the manufacturing technology to a new manufacturer, and to pay OSIs costs for completing clinical trials on the drug. The order also provided for the appointment of an interim trustee to ensure that the development of CP-358,774 is maintained in the future.

10. **Cardinal Health, Inc./ McKesson Corp.**, 12 F. Supp. 2d 34 (D.D.C. 1998). In 1998, the FTC successfully challenged two mergers involving the nation's four largest drug wholesalers -- McKesson merging with AmeriSource and Cardinal Health with Bergen-Brunswig. If the mergers had been permitted, the two survivors would have controlled over 80% of the prescription drug wholesaling market, significantly reducing competition on price and services. The FTC filed the two actions in district court in March 1998, and the case was litigated for approximately seven weeks during June and July. Judge Sporkin enjoined both acquisitions in a 73-page opinion issued at the end of July.

11. **Roche Holding Ltd.**, 125 F.T.C. 919 (1998) (consent order). The complaint charged that Roche's proposed $11 billion acquisition of Corange Limited would harm competition in two U. S. markets: 1) Thrombolytic agents, which are given to heart attack victims as soon as possible after the onset of symptoms in order to dissolve blood clots. Roche, through its majority ownership in Genentech, and Corange, through its Boehringer Mannheim subsidiary, produced the two safest and most effective thrombolytic agents in the U. S. There were no competitive substitutes for thrombolytic agents, and only one other significantly less effective thrombolytic agent was approved for use in the United States; and 2) DAT reagents, which are chemical antibodies that detect whether an illegal substance is present in a urine sample. Workplace DAT screening is conducted at commercial laboratories with instruments designed to use only workplace DAT reagents, and such drug screening is significantly different than hospital-based screening. The DAT reagent market was highly concentrated, and dominated by three of four producers, including Roche and Corange. The complaint alleged that the acquisition, if consummated, would eliminate actual competition between Roche and Corange in the markets for the research, development, manufacture, and sale of cardiac thrombolytic agents and of DAT reagents used in workplace testing. The acquisition would increase

the likelihood that Roche would unilaterally exercise market power in cardiac thrombolytic agents, and the likelihood of collusion or coordinated action among the remaining firms in the DAT reagents market.

The order required Roche to divest or license all of the assets relating to Corange/Boehringer Mannheim's United States and Canadian cardiac thrombolytic agents business to a Commission-approved buyer. Roche was also required to divest, within 60 days of the final order, Corange/Boehringer Mannheim's worldwide DAT reagents business, and to grant to the purchaser an exclusive, world-wide royalty-free license for DAT reagents. Although the divestitures took place within the required time, the Commission included a "crown jewel" provision that would have required a larger asset divestiture had the more narrowly tailored divestiture not occurred.

12. **American Home Products Corp.**, 123 F.T.C. 1279 (1997). The complaint alleged that the acquisition of Solvay's animal health business by American Home Products would harm competition in the U. S. market for three types of "companion animal" vaccines. The acquisition would have given American Home Products a dominant position in the markets for canine lyme vaccines, canine corona virus vaccines, and feline leukemia vaccines, enabling it to unilaterally exercise market power, as well as increasing the likelihood of collusion or coordinated action among the remaining firms. The complaint alleged that American Home Products and Solvay were actual competitors for the three vaccines in the United States; that all three markets were highly concentrated; and that entry into each market was difficult and time consuming, with a number of broad patents governing the manufacture of the three products compounding the difficulty of new entry. The order required American Home Products to divest Solvay's U. S. and Canadian rights to the three types of vaccines to Schering-Plough no later than 10 days after the date on which the order became final. In addition, American Home Products had to provide assistance to Schering-Plough in obtaining United States Department of Agriculture certifications, and to manufacture and supply the three vaccines to Schering-Plough for a period of 24 to 36 months or until Schering-Plough obtained the approvals. The order also included provisions protecting Schering-Plough from patent infringement lawsuits relating to the three vaccines.

13. **Baxter International, Inc.**, 123 F.T.C. 904 (1997) (consent order). The complaint alleged that Baxter's acquisition of Immuno International raised competitive problems in both a current goods market, where the two firms were horizontal competitors, and an innovation market, where neither firm produced a current product but both were among the few firms with a chance to enter the market. Both firms manufactured a wide variety of biological products derived from human blood plasma. The complaint alleged that competition in two plasma products where entry was difficult and time consuming would be harmed : 1) the market for Factor VIII inhibitors for hemophiliacs, which was highly concentrated, as Baxter and Immuno were the only two companies marketing those products in the United States; and 2) the market for fibrin sealants, a product that controls bleeding in surgical procedures, in which there were no current producers in the

United States and Baxter and Immuno were two of only a few companies seeking FDA approval for the products. With no other comparable products slated for launch before late 1999, Baxter and Immuno were posed to be the sole entrants in a market with estimated potential U.S. sales of $200 million. The acquisition would have allowed Baxter to eliminate one of the research tracks and exercise unilateral market power. The order required both divestiture and licensing. In the market for Factor VIII inhibitors, the order required Baxter to divest its Autoplex product to a Commission-approved buyer within four months. The order also required licensure of Baxter's fibrin sealant, and required Baxter to provide the acquirer, Haemacure, with finished product for sale.

14. **J.C. Penney Company/Eckerd Corporation/Rite Aid**, 123 F.T.C. 778, 795 (1997) (consent orders). In October, 1996, Thrift Drug, a subsidiary of J.C. Penny entered into an agreement to purchase 190 drug stores in North and South Carolina from Rite Aid; in November, 1996, Omega Acquisition Corp., another subsidiary of J.C. Penny, entered into an agreement to purchase Eckerd, which owned 1,724 drug stores in thirteen states including North and South Carolina. The complaint charged that the acquisitions would give J.C. Penny a dominant position in Charlotte, Greensboro, and Raleigh-Durham, North Carolina, and Charleston, South Carolina, and allow J.C. Penny to raise prices for pharmacy services to third-party payers. The order required J.C. Penny to divest 161 drug stores: 34 Thrift drug stores in the Charlotte and Raleigh-Durham areas, 110 Rite Aid drug stores in North Carolina, and 17 Rite Aid drug stores in Charleston, South Carolina. The order barred J.C. Penny from acquiring the 127 stores in North and South Carolina until a divestiture agreement approved by the Commission was in place, and in addition, allowed the Commission to appoint a trustee to divest the other 63 drug stores acquired from Rite Aid if the divestitures of the 127 stores were not completed on time. The order also required that the stores be divested to a single pharmacy chain to ensure that the buyer could maintain the size and resources necessary to serve as a competitive pharmacy chain in a PBM's pharmacy network.

15. **CVS Corporation/Revco**, 124 F.T.C. 161 (1997) (consent order); (FTC Press Releases: March 27, 1998 (www.ftc.gov)); Civil Action No. 1:98CV0775 (D.D.C. filed March 26, 1998). The complaint charged that the merger of two large retail drug store chains, CVS and Revco, would give the combined company a dominant position in pharmacy services in Virginia, and in the Binghamton, New York area. According to the complaint, the combined firm would have the ability to increase prices for the sale of retail pharmacy services and restrict services to third-party payers, particularly affecting retail pharmacy networks administered by PBMs which depend on competition among pharmacy chains to keep the cost of pharmacy services competitive. The order required CVS to divest 114 Revco drug stores in Virginia to Eckerd Corporation, and to divest six Revco drug stores in the Binghamton market to Medicine Shoppe. The order allowed the Commission to appoint a trustee who would have the right to divest all 234 Revco drug stores in Virginia and 11 CVS drug stores in the Binghamton market if the required divestitures were not completed three months after the order was finally approved by the Commission. In addition, CVS and Revco signed an asset maintenance agreement requiring them to

preserve the viability and competitiveness of the drug stores to be divested. In March 1998, CVS agreed to pay a $600,000 civil penalty for violating the asset maintenance agreement, the violation of which resulted in the inability of Eckerd to offer pharmacy services that were competitive with the services offered by the pharmacies CVS retained. According to the complaint which was filed in U.S. District Court for the District of Columbia, CVS removed the pharmacy computers and all access to Revco's online data systems prior to the divestiture of the Virginia pharmacies to Eckerd, and then refused to provide Eckerd with the patient pharmacy files in a computerized format that could be used by Eckerd's online computer system.

16. **Rite Aid Corporation/Revco D.S., Inc.**, FTC File No. 961-0020 (preliminary injunction authorized April 17, 1996), (FTC Commission Actions: April 17, 24, 1996, (www.ftc.gov)). On April 17, 1996, the Commission authorized staff to seek a preliminary injunction to block the acquisition of the Ohio based Revco drug store chain by Rite Aid, which is headquartered in Pennsylvania. The complaint charged that the merger of the two largest retail drug store chains in the country would substantially reduce competition for prescription drugs sold in retail pharmacy outlets in numerous geographic areas, including Ohio, Indiana, Maryland, Pennsylvania, Virginia, West Virginia, North Carolina and New York. A week after the Commission's decision to challenge the transaction, Rite Aid notified the Commission that it had abandoned the transaction.

17. **Rite Aid Corporation/Brooks Pharmacies**, FTC File No. 951-0120 (closing letter sent May 31, 1996) (FTC Commission Actions: June 3, 1996 (www.ftc.gov)). In September, 1995, Rite Aid entered into an agreement with the Commission under which it was allowed to acquire several Brooks retail pharmacy stores in Maine from Maxi Drug, Inc. pending completion of the Commission's investigation into possible violation of the antitrust laws. As a condition for the Commission agreeing not to challenge the acquisition in federal district court, Rite Aid agreed to maintain the marketability and viability of Rite Aid's and Brooks' pharmacies, and to restore any lost competition in the relevant markets. Rite Aid reached a similar agreement with the Maine Attorney General's Office, which investigated the case jointly with the FTC. The Commission closed its investigation in June, 1996, citing a consent agreement that Rite Aid entered into with the Maine Attorney General requiring Rite Aid to divest pharmacies in three relevant geographic markets in Maine.

18. **Rite Aid Corporation/LaVerdiere's Enterprises, Inc.**, 118 F.T.C. 1206 (1994) (consent order), Civil Action No. 1:98CV0484 (D.D.C. filed February 27, 1998),125 F.T.C. 846 (1998) (modifying order). The complaint charged that Rite Aid's acquisition of LaVerdiere would substantially lessen competition and increase the prices for prescription drugs sold in retail pharmacy stores in Bucksport and Lincoln, Maine, and in Berlin, New Hampshire. The order required Rite Aid to divest either its own drug stores or the acquired LaVerdiere drug stores in the three cities to a Commission-approved buyer who would operate the stores in competition with Rite Aid. Rite Aid failed to meet

the twelve-month deadline for divestiture, and in February, 1996, the Commission appointed a trustee to divest the drug stores. The trustee found buyers for the Lincoln, Maine store and the Berlin, New Hampshire store, but could not find a buyer for the Bucksport, Maine store. In February, 1998 Rite Aid agreed to pay a $900,000 civil penalty to settle a Commission civil complaint filed in U.S. District Court for the District of Columbia that it failed to comply with the divestiture terms of the 1994 order. Rite Aid then petitioned the Commission to reopen and modify the 1994 order to eliminate the divestiture requirement for the Bucksport, Maine store because neither Rite Aid nor the trustee had been able to find a buyer. The Commission granted the petition in May, 1998, eliminated the divestiture requirement for the Bucksport store, and substituted prior notification and waiting requirements for the prior approval requirement.

19. **TCH Corporation, et al.**, 118 F.T.C. 368 (1994) (consent order). The complaint charged that the merger of two drug store chains, TCH and Payless, would violate the antitrust laws, and lead to higher prices and restricted output in six markets in California, Oregon and Washington: Fort Bragg, Bishop, Mt. Shasta, and Taft, California; Florence, Oregon; and Ellensburg, Washington. TCH already owned the Thrifty drug store chain and Bi-Mart, a chain of membership discount stores. The complaint also alleged that the acquisition would eliminate competition between Thrifty or Bi-Mart and Payless, and increase the likelihood of market control or collusion by Thrifty. The order required TCH to divest to Commission-approved buyers, within one year, the pharmacy business in either the Thrifty, Bi-Mart, or Payless drug stores in the six markets. The order also required TCH to maintain the drugs stores until divested as viable and marketable assets.

20. **Revco D.S. Inc./Hook-SupeRx**, 118 F.T.C. 1018 (1994) (consent order) (FTC Commission Actions: November 1, 1996 (www.ftc.gov)). The complaint charged that the acquisition of the Hook-SupeRx drugstore chain by Revco would substantially reduce competition, raise prices, and reduce service in three markets in Covington, Marion, and Radford, Virginia. The order required Revco to divest either its own pharmacies or the pharmacies acquired from Hook-SupeRx in the three towns within one year, and to maintain the viability of the pharmacies prior to divestiture. The order also provided for the appointment of a trustee if the one year deadline for divestiture was not met. In March, 1995 the Commission approved Revco's divestiture of two Hook-SupeRx pharmacies in Radford. The Commission appointed a trustee in February, 1996, to divest the pharmacies in Covington and Marion because Revco had failed to meet the divestiture deadline called for in the 1994 order. In November 1996, the Commission approved an application from the trustee to divest the drug stores in Marion and Covington to Horizon Pharmacies Inc.

21. **The Dow Chemical Company, et. al.**, 118 F.T.C. 730 (1994) (consent order). The complaint alleged that the purchase of Rugby Darby Group Companies, Inc. (Rugby) by Marion Merrell Dow, Inc. (MMD) would substantially lessen competition by creating a monopoly in the U.S. market for dicyclomine capsules and tablets, a medication used to treat irritable-bowel syndrome. According to the complaint, MMD and Rugby competed

directly and were the only two FDA approved manufacturers of dicyclomine in the U.S. The order required MMD to license dicyclomine formulations and production technology to a third party within12 months, and to contract manufacture dicyclomine for a third party awaiting FDA approval to sell its own dicyclomine. For a period of ten years, the order also required MMD and its parent Dow Chemical to obtain prior approval of the Commission before acquiring any dicyclomine manufacturing, production, or distribution capabilities.

B. Potential Competition Mergers

1. **Cephalon, Inc. and Cima Labs Inc**. C-4121 (consent order issued September 20, 2004) (FTC Commission Actions: September 24, 2004 (www.ftc.gov)). The complaint charged that Cephalon's acquisition of Cima Labs would lessen potential competition and create a monopoly in the market for prescription drugs for the treatment of breakthrough cancer pain (BTCP). Cephalon marketed Actiq (fentanyl), the only FDA approved drug for the treatment of BTCP, and was in the process of developing a sugar free formulation for launch in 2005. Cima Labs was in Phase III clinical trials of Ora Vescent fentanyl, a fast-dissolving, sugar-free fentanyl product, and the firm best positioned to enter the BTCP drug market. The complaint also charged that the acquisition could delay or end the launch of Ora Vescent fentanyl, eliminate the price competition resulting from Cima Labs' entry into the market, and delay entry of generic Actiq into the BTCP drug market. The order requires Cephalon to grant a license and transfer all of the technological knowledge for Actiq to Barr Laboratories, a generic drug manufacturer, in order that Barr can market a generic equivalent of Actiq that will be launched as soon as the FDA approves Cima Labs' Ora Vescent fentanyl. The order also contains provisions to ensure that Barr is able to compete successfully in the BTCP drug market and that Cephalon does not delay the development and launch of Ora Vescent fentanyl.

2. **Pfizer Inc. and Pharmacia Corporation** (See Section IIIA for citation and annotation.)

3. **Baxter International Inc., and Wyeth Corporation** (See Section III A for citation and annotation.)

4. **Amgen Inc. and Immunex Corporation** (See Section III A for citation and annotation.)

5. **Cytyc Corp. and Digene Corp.,** FTC File No.0210098 (preliminary injunction authorized June 24, 2002) (FTC Commission Actions: June 24, 2002 (www.ftc.gov)). The Commission authorized staff to seek a preliminary injunction that would block the proposed merger of two corporations that manufacture and sell tests used in screening for cervical cancer. Cytyc accounted for 93% of the US market for liquid-based Pap tests used in primary screening for cervical cancer. Only one other company, Tripath Imaging, marketed an FDA-approved liquid-based Pap test, and a few other companies may have entered the market in the future. Digene was the only FDA approved supplier of a DNA-based test for the human papillomavirus (HPV) which is thought to be the cause of

cervical cancer. Digene's HPV test was used as a back-up test for equivocal Pap tests but was likely to become a primary screening test, first in conjunction with a liquid Pap test, and then as a stand-alone test. Cytyc was the only company that had FDA approval to market the use of the HPV test from its liquid Pap test samples. If filed in court, the Commission's complaint would have alleged that as a result of the acquisition, Cytyc would be in a position to eliminate Tripath as a competitor by limiting access to Digene's HPV test, and to prevent the entry of other companies that had plans to sell liquid Pap tests in the future. The Commission also cited concerns that the acquisition would eliminate future competition between Cytyc's liquid Pap test and Digene's HPV test as a primary screening test. Within a week after the Commission's decision to challenge the transaction, Digene terminated its acquisition agreement with Cytyc.

6. **Glaxo Wellcome PLC and Smith Kline Beecham PLC** (See Section III A for citation and annotation.)

7. **Hoechst AG and Rhone-Poulenc,** C-3919 (consent order issued January 18, 2000) (FTC Commission Actions: January 28, 2000 (www.ftc.gov)). The complaint charged that Hoechst's acquisition of Rhone-Poulenc would harm competition in the market for direct thrombin inhibitors, which are drugs used in the treatment of blood clotting diseases. Sales of direct thrombin inhibitors total about $15 million in the U.S. market. Hoechst sold Refludan, the only direct thrombin inhibitor currently sold in the U.S. market. Rhone-Poulenc was in the final stages of developing its direct thrombin inhibitor, Revasc, which it licensed from Novartis in 1998. According to the complaint, direct thrombin inhibitors are more effective and safer than other available alternatives for treating blood clotting diseases, and Hoechst and Rhone-Poulenc were each other's closest competitors. The complaint charged that the merger eliminated direct competition between Hoechst and Rhone-Poulenc, and in addition, reduced potential competition and innovation competition among researchers and developers of direct thrombin inhibitors. The order required Hoechst to transfer all of Rhone-Poulenc's rights for Revasc to Novartis or some other third party, and to enter into a short term service agreement with the acquirer of Revasc in order to ensure the continued performance of development work on Revasc.

8. **Zeneca Group plc,** 127 F.T.C. 874 (1999) (consent order). Zeneca's proposed acquisition of Astra raised antitrust concerns based upon potential competition. Zeneca entered into an agreement with Chiroscience Group plc to market and assist in the development of levobupivacaine, a new long-acting local anesthetic being developed by Chiroscience. Long-acting local anesthetics are pharmaceutical products used to relieve pain during the course of surgical or other medical procedures, without the use of general anesthesia, and for certain procedures are the only viable anesthetic. Zeneca proposed to acquire the leading supplier of long-acting local anesthetics, Astra, which was one of only two companies approved by the FDA for the manufacture and sale of these kinds of drugs in the United States. Although Zeneca did not currently participate in the market for long-acting local anesthetics, by virtue of its agreement with Chiroscience, it was an

actual potential competitor. The Commission's complaint alleged that the acquisition would result in the elimination of a significant source of new competition.

The consent order required Zeneca to transfer and surrender all of its rights and assets relating to levobupivacaine to Chiroscience no later than 10 business days after the date the Commission accepted the agreement for public comment. The assets to be transferred to Chiroscience consisted principally of intellectual property and know-how, and included all of the applicable patents, trademarks, copyrights, technical information, and market research relating to levobupivacaine. During a transitional period, Zeneca was required to continue carrying out certain ongoing activities relating to the commercialization of levobupivacaine, including manufacturing, regulatory, clinical, development, and marketing activities. Zeneca was also required to divest its approximately three percent investment interest in Chiroscience.

9. **Hoechst AG,** 120 F.T.C. 1010 (1995) (consent order). The complaint alleged that potential competition would be harmed in four markets if Hoechst, a German pharmaceutical company, acquired Marion Merrill Dow in a $7.1 billion dollar merger that at the time created the world's third largest pharmaceutical company. The four markets accounted for $1.4 billion in U. S. sales, and affected hundreds of thousands of consumers who suffered from hypertension, angina, arteriosclerosis, and tuberculosis. The relevant markets all featured current production by one of the merging firms and the potential for the other firm to enter the market with a new product: 1) The largest market was the $1 billion once-a-day diltiazem market, where MMD's Cardizem CD had a dominant share. Prior to the merger, Hoechst and Biovail were jointly developing Tiazac to compete against Cardizem CD. Although Hoechst returned the rights to Tiazac to Biovail before the merger agreement was finalized, the order also required Hoechst to provide Biovail with a letter of access to toxicology data necessary to secure FDA approval, to return to Biovail and refrain from using any confidential information, and to end and refrain from litigations or citizen petitions regarding Tiazac; 2) Hoechst marketed Trental, the only drug that was currently approved by the FDA for intermittent claudication, a painful leg cramping condition that affects over 5 million people in the U.S. MMD had rights to Beraprost, one of the few drugs in development for this condition before the merger. The order required Hoechst to divest either Trental or Beraprost; 3) MMD marketed Pentasa, one of two oral forms of a drug used to treat the gastrointestinal diseases of ulcerative colitis and Crohn's Disease, which affects over 1 million people in the U.S. Hoechst was one of only a few firms developing a generic form of this drug. Hoechst was required to divest one of the two drugs; 4) MMD marketed a brand of the TB drug rifampin. Hoechst was one of only a few firms developing a generic form of rifampin. Hoechst was required to divest one of the two drugs. In each market, Hoechst was required to divest either the current line of business or the potential new product to a Commission-approved buyer that would develop and market it; and to prevent the deterioration of the assets involved, maintain its research and development efforts at pre-merger planned levels pending divestiture, and provide technical assistance and advice to the purchasers in obtaining FDA approval.

C. Innovation Market Mergers

1. **Pfizer Inc. and Warner-Lambert Company** (See Section III A for citation and annotation.)

2. **Baxter International, Inc.** (See Section III A for citation and annotation.)

3. **Ciba-Geigy, Ltd.**, 123 F.T.C. 842 (1997) (consent order). The complaint alleged that the merger of Ciba-Geigy and Sandoz would result in an anticompetitive impact on the innovation of gene therapies. The firms' combined position in gene therapy research was so dominant that other firms doing research in this area needed to enter into joint ventures or contract with either Ciba-Geigy or Sandoz in order to have any hope of commercializing their own research efforts. Without competition, the combined entity could appropriate much of the value of other firms' research, leading to a substantial decrease in such research. In addition, there was direct competition between the two companies with respect to specific therapeutic products. At the time of the merger, no gene therapy product was on the market, but potential treatments were in clinical trials. The complaint noted that the first products would not be available until the year 2000, but that the market could grow to $45 billion by the year 2010. The complaint identified five relevant product markets, all of which were located in the United States. The first relevant market encompassed the technology and research and development for gene therapy overall. The other markets each involved the research and development, manufacture, and sale of a specific type of gene therapy: cancer; graft-versus-host disease (GVHD); hemophilia; and chemoresistance. In the market for overall gene therapy, the complaint alleged that Ciba and Sandoz controlled the key intellectual property rights necessary to commercialize gene therapy products. For each of the four specific gene therapy markets, the complaint asserted that the relevant market was highly concentrated and that Ciba and Sandoz were the two leading commercial developers of the gene therapy product. Moreover, entry into the gene therapy markets was difficult and time-consuming because any entrant would need patent rights, significant human and capital resources, and FDA approvals.

   The order centered on the intellectual property rights. The new company, Novartis, was required to grant to all requesters a non-exclusive license to certain patented technologies essential for development and commercialization of gene therapy products. Depending on the patent, Novartis could receive an up-front payment of $10,000 and royalties of one to three percent of net sales. Novartis also was required to grant a non-exclusive license of certain technology and patent rights related to specific therapies for cancer, GVHD, and hemophilia to a Commission-approved licensee. Novartis could request from the licensee consideration in the form of royalties and/or an equivalent cross-license. Further, the merged company could not acquire exclusive rights in certain intellectual property and technology related to chemoresistance gene therapy.

4. **The Upjohn Co.**, 121 F.T.C. 44 (1996) (consent order). The complaint alleged that the acquisition of Pharmacia Aktiebolag by Upjohn would harm competition in the market for topoisomerase I inhibitors, drugs used in conjunction with surgery to treat colorectal cancer. The merging firms were two of only a very small number of companies in the advanced stages of developing the drugs. Upjohn's CPT-11 was the most advanced product, with Pharmacia's 9-AC product a few years behind. Because it would take the other companies years to reach the advanced stage of development, the complaint alleged that it was not likely that other firms would constrain the merged firm from terminating development of one of the products or raising prices. The order required the merged firm to provide technical assistance and advice to the acquirer toward continuing the research and development of 9-AC.

5. **Glaxo PLC**, 119 F.T.C. 815 (1995). In *Glaxo*, the complaint alleged harm to innovation markets where the merging parties -- Glaxo and Burroughs Wellcome – were the two firms furthest along in developing an oral drug to treat migraine attacks. Current drugs existed to treat migraine, but they were available only in injectable form and were not sufficiently substitutable to be included in the relevant market. The complaint alleged that the acquisition would eliminate actual competition between the two companies in researching and developing migraine remedies. The complaint also alleged that the acquisition would reduce the number of research and development tracks for these migraine remedies, and increase Glaxo's unilateral ability to reduce research and development of these drugs. The order required the combined firm to divest Wellcome's assets related to the research and development of the migraine remedy. Among those assets were patents, technology, manufacturing information, testing data, research materials, and customer lists. The assets also included inventory needed to complete all trials and studies required to obtain FDA approval.

D. Vertical Mergers

1. **Merck/Medco,** 127 F.T.C. 156 (1999) (consent order). The complaint alleged that Merck's ownership of Medco, a pharmacy benefits manager ("PBM"), would allow Merck to favor its own drugs on Medco's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The order requires Merck/Medco to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee.

2. **Eli Lilly/PCS** 120 F.T.C. 243 (1985) (consent order); 127 F.T.C. 577 (1999) (set aside order). The complaint alleged that Lilly's acquisition of PCS, a pharmacy benefits manager ("PBM"), from McKesson Corp. would allow Lilly to favor its own drugs on PCS's formularies. A PBM's formulary often affects drug choice and reimbursement under certain health plans. The order requires Lilly/PCS to maintain an open formulary, whereby drugs are selected according to objective criteria by an independent panel of physicians, pharmacists, and others, known as a Pharmacy and Therapeutics Committee.

The order was set aside in 1999 when Lilly sold PCS to Rite Aid Corp.

IV. INDUSTRY GUIDANCE STATEMENTS

A. Advisory Opinions

Under the policy statements, the Commission has committed to responding within 90 days to requests for advice from health care plans or providers about matters addressed by the "safety zones" or the non-merger policy statements; and within 120 days to requests for advice regarding multiprovider networks and other non-merger health care matters. The response period will commence once all necessary information has been received by the Commission.

Information regarding advisory opinions is set forth in the Topic And Yearly Indices of Health Care Advisory Opinions By Commission And By Staff. The index and the text of the advisory opinions issued since October, 1993, are available at the FTC's web site at http://www.ftc.gov.

B. Citizen Petition to the Food and Drug Administration

The Bureau of Competition and the Policy Planning Staff of the Federal Trade Commission submitted a Citizen Petition to the Commissioner of Food and Drugs on May 16, 2001, in which it requested guidance on the FTC staff's interpretation of certain FDA regulations related to patent listings in the Orange Book. The petition sought the FDA's views on the two prong criteria that a patent must meet under 21 C.F.R. § 314.53 (b) before it can be listed in the Orange Book. The petition also asked for guidance on other patent listing issues, including whether an NDA holder can list a patent for an unapproved aspect of an approved drug, or a chemical compound not approved for use as the drug substance in an approved drug product, and the meaning of the term "drug product" as it relates to infringement analysis under the regulation. FDA never formally responded to our citizen's petition, but instead issued proposed regulations on October 24, 2002, to modify in part its regulations concerning Orange Book listings. Staff submitted comments to the proposed regulations on December 23, 2002. FDA's proposed regulations remain pending.

V. AMICUS BRIEFS

1. **Brief of Amicus Curiae Federal Trade Commission Supporting Appellant's Combined Petition for Rehearing and Rehearing En Banc**, Case No. 03-CV-10167 (Fed Cir.), filed February 11, 2005, (FTC Commission Actions: February 11, 2005 (www.ftc.gov); **Brief of Amicus Curiae Federal Trade Commission Supporting Appellant and Urging Reversal** in **Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.**, Case No. 04-1186 (Fed. Cir.), filed March 31, 2004; (FTC Commission Actions: April 2, 2004 (www.ftc.gov). Teva sought a declaratory judgment that its generic version of Pfizer's sertraline hydrochloride drug would not infringe a patent held by Pfizer (or that the patent was invalid). The district court dismissed Teva's complaint for lack of subject

matter jurisdiction. The Commission's brief explains that declaratory actions by generic companies (such as Teva) play a vital role in the Hatch-Waxman regime by providing these applicants with the opportunity to eliminate bottlenecks that can delay them from obtaining FDA approval to market their product. The brief argues that the district court applied the wrong test to assess jurisdiction in the Hatch-Waxman cases brought by a "second" generic applicant, such as Teva. It argues that the court failed to take account of the fact that, unless Teva can obtain a court decision regarding Pfizer's patent, the FDA cannot give Teva approval to market its generic drug until 180 days after the first generic applicant (Ivax Pharmaceuticals) enters the market with its version. The brief also explained that the district court's holding will leave subsequent generic applicants (such as Teva) powerless to prevent brand-name manufacturers and first generic applicants from greatly delaying other generic manufacturers from entering the market. On January 21, 2005, the Court of Appeals for the Federal Circuit affirmed the judgment of the district court. On February 11, 2005, the Commission filed a second amicus brief in support of Teva's combined petition for rehearing and rehearing en banc, arguing that the district court had not applied the proper standard in evaluating whether there was an actual controversy between Teva and Pfizer.

2. **Memorandum of Law of Federal Trade Commission as Amicus Curiae Concerning Torpham's Cross Motion for Entry of An Amended Order** in **Smithkline Beecham Corporation v. Apotex Corporation**, Case No. 99-CV-4304 (E.D. Pa., January 29, 2003); (FTC Commission Actions: January 29, 2003 (www.ftc.gov). Smithkline Beecham (now GlaxoSmithKline) sued Apotex, a generic drug manufacturer, for infringing two patents on it's antidepressant drug Paxil. After the district court ruled the Glaxo patents invalid, Apotex filed a motion to have the two patent listings removed from the Orange Book. In response to this motion, the Commission filed an amicus brief arguing that improper listings in the Orange Book effect competition and harm consumers. The Commission detailed the anticompetitive effects resulting from improper listings, including additional 30-month stays of FDA approval, that ultimately delay the entry of generic drugs. The Commission also argued that consumers benefit from the large savings that result from the competition provided by generic drugs, an estimated $30 million dollars a month in the case of a generic Paxil. The Commission argued that a de-listing remedy is consistent with the Court's judgment of invalidity, because it would prevent the branded manufacturer from benefitting from the 30-month stay of FDA approval even after a judgment of invalidity.

3. **Memorandum of Law of Amicus Curiae the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss in In re: Buspirone Patent, Antitrust Litigation**, MDL Docket No. 1410 (JGK) (S.D. N.Y., January 8, 2002). The In re: Buspirone Patent and Antitrust Litigation involves claims by generic drug manufacturers that Bristol-Myers-Squibb, manufacturer of the brand drug BuSpar, attempted to delay generic competition to BuSpar, in violation of Section 2 of the Sherman Act, when it filed misrepresentative claims to the FDA concerning the listing of a newly issued patent in the Orange Book. BMS filed a motion to dismiss the case on the grounds that the listing is

valid petitioning to a government agency and therefore immune from the antitrust laws under *Noerr*. In its amicus brief, the Commission argued that Orange Book filings are not immune from Sherman Act liability under *Noerr* because: 1) they are ministerial filings and not legitimate petitions intended to influence governmental decision-making; 2) they do not constitute adversarial pre-litigation threat letters incidental to litigation, and 3) they are not necessary for patent infringement litigation. The Commission also argued that even if the Orange Book listings constitute "petitioning" under *Noerr*, the misrepresentation and sham exceptions may deprive BMS of *Noerr* immunity. The court ruled that the listing of the buspirone patent in the Orange Book was not valid petitioning of a government agency and therefore not protected under *Noerr;* in addition, according to the court, the plaintiffs had shown that there was reason to warrant an exception to *Noerr* immunity because BMS had obtained the patent fraudulently and attempted to maintain a monopoly by bringing the patent litigation.

4. **Brief of the Federal Trade Commission as Amicus Curiae in <u>American Bioscience, Inc. v. Bristol-Myers Squibb Co.</u>,** No. CV-00-08577 WMB (AJWx) (C.D. Cal., September 1, 2000). American Bioscience, Inc. (ABI) sued Bristol-Myers Squibb, the maker of Taxol, a drug used to treat cancer, to force it to list a patent on the FDA Orange Book, and obtained an unopposed temporary restraining order (TRO). As part of a proposed settlement between ABI and Bristol, the parties agreed that (1) the court would enter a finding that ABI's patent should be listed in the Orange Book, and (2) Bristol would maintain the listing of the patent in the Orange Book. In its amicus brief, the Commission asked the judge to consider the anticompetitive ramifications of the proposed settlement. First, another court might find any judicial finding that the patent met the statutory requirements for listing on the Orange Book persuasive, or even conclusive, thus hindering a generic company's attempt to challenge the listing. Second, the order to maintain the listing would conflict with any later court order requiring Bristol to delist the patent, and resolving the conflicting court orders could further forestall generic entry. The brief also announced the Commission's investigation of ABI and Bristol, and asked the court to consider its pendency when deciding on the proposed settlement. The court ultimately determined that ABI could not maintain a private action under the Food, Drug, and Cosmetics Act, dissolved the TRO, and ordered Bristol to delist the ABI patent.

VI. INDICES

A. Table of Cases

B. Table of Briefs